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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
CINCINNATI DISTRICT OFFICE
1141 Central Parkway
Cincinnati, OH 45202-1097

June 16, 1997

WARNING LETTER
CIN-WL-97-420

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dana Adams, General Manager
Professional Medical Equipment Services
4719 Fulton Dr., NW
Canton, OH 44718

Dear Mr. Adams:

The Food and Drug Administration conducted an inspection on May 28 and 29, 1997 of your liquid and gas-oxygen transfilling facility. Our investigator documented significant deviations from the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals [Title 21 Code of Federal Regulations (CFR) Parts 210& 211]. These deviations cause your drug product, Oxygen U.S.P. to be adulterated within the meaning of Section 501(a) (2) (B) of the Federal Food Drug and Cosmetic Act (the Act).

The deviations documented during the inspection included:

- Filling logs for liquid oxygen are incomplete in that they are not reviewed, signed and dated by management. Gas transfilling batch records are incomplete in that results of prefill inspections, fill inspections, and results of purity and identification tests are not always entered.

- failure to properly operate the [redacted] oxygen analyzer used to assay the transfilled cylinders - Examples include the analyzer was not being calibrated each day of use; the written procedure for calibration was not always followed and the written procedure for operation of the analyzer was incomplete.

- failure to have written, approved and complete procedures for the testing and receiving of liquid oxygen; distribution and recalls; testing transfilled cylinders; calibration of the pressure gauges used in transfilling oxygen and training procedures.

- incomplete documentation that individuals have received necessary training to transfill medical oxygen

The violations identified above are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder are being met. We are enclosing a speech entitled "Fresh Air 96 - A

Look at FDA's Medical Gas Requirements" by Duane Sylvia, Consumer Safety Officer, Center for Drug Evaluation and Research on December 4, 1996, which provides useful information in controlling medical gas repacking.

Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this into account when considering the award of contracts. By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care products in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include seizure and injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the Food and Drug Administration, Compliance Branch, 1141 Central Parkway, Cincinnati, Ohio 45202 to the attention of Lawrence E. Boyd, Compliance Officer.

Sincerely,

John R. Marzilli
District Director
Cincinnati District

Enclosure

cc. Peter Reibold, President
Columbus/CSA-HS Greater Cleveland Healthcare
2351 E. 22nd. Street
Cleveland, OH 44115

Health Care Finance Administration
Chief Carrier Operations Branch
Division of Medicine
105 West Adams Street, 15th Floor
Chicago, IL 60603-6201